



ATTACHMENT A

REMARKS

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Claims 40-57 stand pending in the present application. By this Amendment,

Applicant has amended claims 40 and 42 and added new claim 57. Applicant respectfully submits that the present application is in condition for allowance based on the discussion which follows.

Claims 40-56 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,769,974 to Davis in view of U.S. Patent No. 5,656,285 to Sablotsky et al (hereinafter "Sablotsky").

Applicant gratefully appreciates the Examiner extending an in-person interview with its representative, Stephan Weyer, to discuss this case. During that interview, Applicant distinguished the present continuous process for manufacturing a transdermal patch which holds an active substance which is in the form of a gel or liquid filled pack known in the art as a reservoir pack or liquid/gel filled pack. In accordance with that interview, by this Amendment, Applicant has amended claim 40 which now more clearly recites that the transdermal patch holds an active substance in the form of a liquid or gel and includes a permeable membrane which is permeable to the active substance.

Applicant respectfully submits that claim 40 is not obvious by the prior art of record. The, *arguendo*, combined teachings of Davis in view of Sablotsky fail to teach each and every element of the claimed invention namely a continuous process which produces a transdermal patch which holds an active substance in the form of a liquid or gel where the transdermal patch includes a permeable membrane permeable to the active substance. Thus, the combination of Davis in view of Sablotsky fails to teach or

suggest a process for manufacturing a pouch filled with a liquid or gel active substance which is permeable to a permeable membrane.

Further, one of ordinary skill in the art would not combine the art of food packaging with drug manufacturing to make the present invention obvious.

Davis is directed to producing a food-filled pouch and as such produces a non-permeable bag material for containing the food substance.

Sablotsky is directed to a continuous process for manufacturing matrix style transdermal patches. Matrix patches are fundamentally different from reservoir patches such as in the present invention. A matrix patch typically has multiple layers which include a backing layer, drug-in-adhesive formulation layer and a release liner layer. The process for forming a matrix patch is completely different from one used for creating reservoir patches which is quite evident in that a matrix patch, having no liquid or gel material, will not include a filling step where a liquid or gel is introduced into the patch.

It is inappropriate to combine the art of a food packaging process (Davis) with a transdermal matrix-type patch process (Sablotsky). One of ordinary skill in the art would not be motivated nor is there any suggestion to combine these two very dissimilar arts. For example, the accuracy and FDA regulation necessary for the manufacturing of a drug product is not present in the food art. Thus, one of ordinary skill in the art wishing to develop a better transdermal liquid/gel filled patch drug device would not be motivated to combine the drug manufacturing art of Sablotsky with a food packaging process of Davis. The lack of motivation is exemplified when considering that a food process tends not to provide the necessary accuracy required in the drug art.

Moreover, prior to the present invention, it is unlikely that one of ordinary skill in the art would consider that the present process would be successful in forming a liquid/gel filled patch using a continuous process due to prior processes which resulted in drug leakage and inaccurate dosage. Although the manufacturing of matrix patches use a continuous process, prior to this invention liquid/gel patches have previously required an intermediate processing and thus, not produced using a continuous process. This limitation (i.e., intermediate step) was necessary due to the nature of a form-fill-seal process where the reservoir/patch was filled before sealing and cutting. The prior technology employed to achieve manufacturing of prior liquid/gel packs was predominantly the blister-pack process. However, historically such intermediate processing step methods place the extremely sensitive membrane webs, e.g., the permeable membrane, under stress as well as increase the risk of liquid/gel leakage into the sealing zones if dosing occurs before the seals are formed. The present continuous process overcomes the prior limitations and provides for improved productivity, efficiency, lower material wastage and ultimately lower unit costs than both prior liquid/gel patch manufacturing processes and matrix patch manufacturing processes. Thus, the unlikelihood of success of using a continuous process in forming a reservoir patch and the commercial benefits of the present method make the present process unobvious over Davis in view of Sablotsky.

Based on the foregoing, Applicant submits that claims 40-56 are not obvious in view of Davis in combination with Sablotsky.

By this Amendment, Applicant has added new claim 57 based on an optional further embodiment originally presented in claim 40. Applicant submits that claim 57 is

not obvious for at least the same reasons as discussed above with regard to claims 40-56.

By this Amendment, Applicant has amended claim 43 to correct its dependency and to amend the claim language to be more consistent with the terminology in the art. Subject matter basis for the amendment to claim 43 can be found in the specification as filed on page 5, line 35 through page 6, line 3; and page 12, lines 15-20. Thus, the amendment to claim 43 does not constitute new matter.

In view of the foregoing, Applicant respectfully submits that the present application is in condition for allowance, which action is promptly and respectfully solicited.

END REMARKS



ATTACHMENT B
Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

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1-39. (Canceled)

40. (Currently Amended) A continuous process for forming a transdermal patch, ~~which comprises holding an active substance, said process comprising the steps of:~~

continuously feeding at a linear speed a first strip of materials comprising a disposable layer, a layer of adhesive and a layer of a permeable membrane permeable to the active substance;

continuously feeding in close proximity and in face-to-face relationship with the first strip at least one second strip formed of impermeable backing material(s), at the same linear speed;

passing the first and second strips together through a first sealing station at which at least the opposed longitudinal edge regions of the strips are secured together, ~~optionally with intermediate regions of the strips being secured along their lengths, so as to form at least one elongate chamber~~;

passing the first and second strips joined at least at their longitudinal edges, through a second sealing station at which the strips are sealed to each other transversely at intervals along the strips, whereby the or each chamber becomes an open-topped pouch;

introducing an accurate predetermined dosage of a liquid or gel containing an active substance into the pouch or pouches, once formed, in synchronous with the linear speed; and

sealing the pouches along their previously open edges so as to form completely sealed pouches thereby forming the transdermal patch.

41. (Previously Presented) A continuous process as claimed in claim 40, in which, at the second sealing station the previously open region of a pouch or pouches is sealed and the sealing simultaneously closes the adjacent region of the pouch or pouches immediately upstream of the first mentioned pouch or pouches.

42. (Previously Presented) A continuous process as claimed in claim 40, further including a separation cutting step in which a transverse cutting exercise takes place so as to separate one sealed pouch containing the active substance from the adjacent pouches upstream and downstream.

43. (Currently Amended) A continuous process as claimed in ~~claim 40, in which a "kiss-cut" function is provided at the claim 42, wherein the separation cutting step comprises separating one sealed pouch from the adjacent pouches along a tear-tab.~~

44. (Previously Presented) A continuous process as claimed in claim 40, in which the two strips are first brought together and sealed along their longitudinal edges and separately or simultaneously one or more additional longitudinal seals are created intermediate the edge region seals thereby creating two or more laterally adjacent pouches across the width of the strips.

45. (Previously Presented) A continuous process as claimed in claim 44, in which the laterally adjacent pouches are separated in a longitudinal cutting step in which rollers, at least one of which has a cutting edge, act on opposite sides of the join strips, so as to separate the laterally adjacent pouches.

46. (Previously Presented) A continuous process as claimed in claim 40, further comprising a gas flushing step in which the or each pouch is flushed with gas during the step in which liquid or gel is introduced.

47. (Previously Presented) A continuous process as claimed in claim 46, in which in the gas flushing step, a small bore tube is placed adjacent a filling tube and flushing gas is ejected from the small bore tube directly into the pouch.

48. (Previously Presented) A continuous process as claimed in claim 40, in which the filling and sealing steps are effected at a pressure lower than atmospheric pressure.

49. (Previously Presented) A continuous process as claimed in claim 40, in which the sealing of adjacent strips is effected by opposing pairs of longitudinal or transverse sealing devices.

50. (Previously Presented) A continuous process as claimed in claim 49, in which the means by which the liquid or gel containing the active substance is introduced takes the form of a filling tube which is inserted into the or each pouch.

51. (Previously Presented) A continuous process as claimed in claim 50, in which the lower end of the filling tube is at a level considerably below the axis of rotation of the sealing devices.

52. (Previously Presented) A continuous process as claimed in claim 50, in which the filling tube is positioned at a level just above where the transverse sealing devices are disposed.

53. (Previously Presented) A continuous process as claimed in claim 49, in which the filling tube is positioned at a level just above where the transverse sealing devices are disposed.

54. (Previously Presented) A continuous process as claimed in claim 49, further comprising the step of adjusting the number of pouches being produced side by side, by adding or removing one or more pairs of longitudinal sealing devices and adjusting the location of the intermediate sealing devices.

55. (Previously Presented) A continuous process as claimed in claim 49, further comprising the step of adjusting the size of the pouches, by adjusting the timing of transverse sealing devices, thereby changing the length of the pouches.

56. (Previously Presented) A continuous process as claimed in claim 40, in which the strips are fed in a substantially vertical direction and the liquid or gel containing an active ingredient is introduced into the pouch or pouches in a substantially vertical direction.

57. (New) A continuous process as claimed in claim 40 wherein the intermediate regions of the strips are secured along their lengths so as to form at least one elongated chamber.